

## **Response**

Claims 1, 3-5, and 7-15 of the subject application are pending. Applicant has amended claims 1, 11, and 15. Applicant has not canceled or added any claims. Accordingly, claims 1, 3-5, and 7-15 are presently being examined.

## **Support for the Amendments**

Applicant has amended claim 1 in order to more clearly describe and distinctly claim the subject matter of applicant's sugar-free soft chew tablet composition. Specifically, applicant has deleted the word "comprising" from claim 1 and substituted therefore "consisting essentially of". Applicant has also amended claim 1 to recite "water in an amount up to about 5% by weight". Applicant has further amended claims 11 and 15 to remove reference to cellulosic materials. Applicant has entered these amendments in order to overcome the Examiner's rejections. These amendments to the claims are fully supported in the specification as originally filed, and thus no new matter is introduced by these amendments in accordance with 35 U.S.C. §132. Accordingly, applicant requests entry of these amendments.

## **Examiner's Detailed Action.**

The Examiner states that the amendment filed February 7, 2008 has been received and entered, claim 6 has been cancelled in this amendment, and claims 1, 3-5 and 7-15 are currently pending. The Examiner states that applicant elected with traverse hydrogenated starch hydrolyzate and lactitol for species A, partially hydrogenated soybean oil for species B, lecithin for species C, dietary fibers for species D, carrageenan for species E, hydroxypropylmethyl cellulose for species F, and psyllium for species G. The Examiner states that applicant has cancelled the elected species for species C, i.e. lecithin, and accordingly the search has been extended to polyglycerol esters. The Examiner points out that claims 1, 3-5 and 7-15 are examined on the merits in regard to the elected species and that

applicant's arguments submitted February 7, 2008 have been fully considered but are moot in light of the new grounds of rejection presented below.

In summary, applicant submits that *Bunick et al.* and *Walter et al.* are not properly combinable. There is no teaching or disclosure in *Bunick et al.* or *Walter et al.* to employ the emulsifier in the chewy supplemental dietary fiber fortified taffy sugar confection of *Walter et al.* in the sugarless chewable aerated confectionery frappe composition of *Bunick et al.* Even if the references were properly combinable, the combination of *Bunick et al.* and *Walter et al.* would still not provide applicant's sugar-free soft chew tablet composition because *Bunick et al.* teaches the use of cellulose derivatives that reduce the inherent excessive cold flow and stickiness associated with hydrogenated starch hydrolysate confections and *Walter et al.* teaches the use of sugars not applicant's sugar-free polyol materials.

#### **Withdrawal of Claim Objections**

Applicant acknowledges that the Examiner has withdrawn the objection to claim 1 on the basis of informalities in view of applicant's amendments.

#### **Withdrawal of Rejection of Claims 1 and 3-15 under 35 U.S.C. §102(b) as being anticipated by *Bunick et al.***

Applicant notes that the Examiner has withdrawn the rejection of claims 1 and 3-15 under 35 U.S.C. §102(b) as being anticipated by United States pat. no. 4,714,620 (*Bunick et al.*) in view of applicant's amendments.

#### **New Rejection of Claims 1, 3-5 and 7-15 under 35 U.S.C. §103(a) as being obvious over *Bunick et al.* in view of *Walter et al.***

The Examiner has newly rejected claims 1, 3-5 and 7-15 under 35 U.S.C. §103(a) as being unpatentable over United States Pat. No. 4,714,620 (*Bunick et al.*) in view of United States Pat. No. 5,476,678 (*Walter et al.*). The Examiner states that *Bunick et al.* teaches a

soft, sugar free, chewable nougat composition, containing 35% to 89% hydrogenated starch hydrolyzate, 1% to 10% cellulose, 2% to 10% fat, and 7% to 12% water (see claim 1). The Examiner states that the fat is claimed as partially hydrogenated oils including soy oil (claim 5); the composition contains up to 45% lactitol and/or maltitol (claim 10); the cellulose are fibers and include hydroxypropylmethylcellulose (claim 2); the composition contains up to 5.5% of a thickening agent such as psyllium and/or carrageenan (claim 7); and the composition can be shaped into any desirable form including a tabloid shape (claim 8, lines 42-45). The Examiner states that "tabloid" is a type of tablet (<http://dictionary.reference.com/browse/tabloid>).

The Examiner concedes that *Bunick et al.* does not teach including emulsifiers in the composition. The Examiner argues that *Walter et al.* teaches including emulsifiers such as polyglycerol esters in nougat compositions in the amount of 2%-5% and that the inclusion of emulsifiers improves the composition because the emulsifiers improve the mouth feel of the composition and reduce the composition's stickiness (abstract, column 1, and column 6, lines 45-55). The Examiner concludes that one of ordinary skill would reasonably expect that including emulsifiers of *Walter et al.* in the composition of *Bunick et al.* would improve the composition of *Bunick et al.* because there would be a reduced stickiness and an improved mouth feel. The Examiner argues that *Bunick et al.* and *Walter et al.* together teach a composition that contains all of the same ingredients as claimed by applicant in the same amounts claimed by applicant. The Examiner concedes that *Bunick et al.* and *Walter et al.* do not specifically teach that the composition is reheatable but argues that since the references teach using the same ingredients, the reference composition would be reheatable. The Examiner also concedes that *Bunick et al.* and *Walter et al.* do not specifically teach adding the ingredients in all of the amounts claimed by applicant but argues that the amount of a specific ingredient in a composition is a result effective parameter that a person of ordinary skill in the art would routinely optimize. Absent some demonstration of unexpected results, the Examiner concludes that optimization of ingredient amounts would have been obvious. Applicant's claims as amended obviate the Examiner's rejections.

Applicant's invention, as amended, provides a sugar-free soft chew tablet composition consisting essentially of a reheatable composition that includes a) a mixture of two polyols

present in an amount from about 15% to about 80%, by weight, the polyols being selected from the group consisting of hydrogenated starch hydrolysates, maltitol, lactitol, and mixtures thereof; b) an emulsifier system present in an amount from about 1.0% to about 30%, by weight, wherein the emulsifier is selected from the group consisting of acetylated mono glycerides, glycerol esters, glycerol monostearate, polyglycerol esters, propylene glycol esters, sorbitan esters, polysorbate esters, sodium laurel sulfate, polyethylene glycols, sorbitol mono-, di- and tri-stearates and mixtures thereof; c) water in an amount up to about 5% by weight; and d) an active agent in an amount from about 0.1% to about 70%, by weight, that is added to the reheatable composition either upon cooling or after the composition has been cooled and later reheated to form the soft chew tablet composition. (Applicant's specification at claim 1)

The *Bunick et al.* reference discloses a sugarless chewable aerated confectionery composition which comprises a hydrogenated starch hydrolysate in an amount of about 35% to about 89%, cellulotics in an amount of about 1% to about 10% wherein the cellulotics are a non-water soluble and a water-soluble cellulosic such that the ratio of water-soluble to non-water soluble cellulosic is about 1:3 to about 3:1, a whipping agent in an amount of about 0.1% to about 7.5%, fat in an amount of about 2% to about 10%, and a final water content of about 7% to about 12%. (*Bunick et al.* at claim 1).

*Bunick et al.* states that "[n]ougats are perhaps the most complex and difficult of the generic confectionery bases to prepare. They are aerated confections whose density largely depends on a frappe element and texture on a syrup element along with its subsequent crystallization. The preparation of soft confections such as nougat, involves the combination of two primary components thereof, namely a high boiling syrup such as corn syrup or the like, and a relatively light textured frappe, generally prepared from gelatin, egg albumen, milk proteins such as casein, and vegetable proteins such as soy protein, and the like." *Bunick et al.* at col. 1, lines 6-17.

The *Walter et al.* reference discloses a chewy supplemental dietary fiber fortified taffy confection consisting essentially of a dry mixture of ingredients selected from the group consisting of maltodextrin, fondant sugar, powdered sugar, cream flavor, organic food acids, and yogurt powder and mixtures thereof; an emulsifier blend comprising a plastic mono- and

diglyceride, and at least 17%  $\alpha$ -monoglyceride content and a solid mono- and diglyceride, and at least 40% mono-glyceride content and at least 48% total mono glycerides content; a syrup system; a fortificant; a flavoring; and uncoated supplemental dietary fiber added to the taffy confection in an amount such that the taffy confection has a total dietary fiber content of between 5%-30% by weight and wherein the fiber comprises fine particle size guar gum and gum arabic, and apple pectin (claim 1). *Walter et al.* further provides that the emulsifier blend may comprise between 2 to 4% by weight (claim 5).

Applicant's sugar-free soft chew tablet composition does not require cellulosics in the base formulation. As set out above, applicant has amended dependent claims 11 and 15 to delete cellulosics. *Bunick et al.* requires the use of cellulosics. *Bunick et al.* incorporates cellulosics and states that "it is believed that incorporation of the cellulosics reduce the inherent excessive cold flow and stickiness associated with hydrogenated starch hydrolysate confection by occupying surface space, building body to the final piece and sorbing moisture." *Bunick et al.* at col.3, lines 19-23. This is not applicant's sugar-free soft chew tablet composition in which an active agent may be added to the reheatable composition either upon cooling or after the composition has been cooled and later reheated to form the soft chew tablet composition. (Applicant's claim 1)

As set out above, applicant has also amended independent claim 1, and the claims dependent thereon, to delete the term "comprising" and substitute therefore the term "consisting essentially of."

The term "consisting essentially of" is a term of art used in the chemical patent practice, which has an accepted meaning. The term "consisting essentially of" excludes ingredients in a claim, which would affect the basic and novel characteristics of the product defined in the claim. *In re Garnero*, 412 F2d 276, 162 USPQ 221 (CCPA 1969). Where the omission of ingredients present in the prior art composition results in a composition having basic or novel characteristics not possessed by the prior art, the use of the term "consisting essentially of" in the claims to exclude the omitted ingredients avoids anticipation. *In re DeLalarta*, 337 F2d 870, 143 USPQ 256 (CCPA 1964). The term "consisting essentially of" leaves the claim open for inclusion of unspecified ingredients, which do not materially

affect the basic and novel characteristics of the composition. *Application of Janakirana-Rao*, 317 F.2d 951, 952, 137 U.S.P.Q. 893, 894 (CCPA 1963).

By amending claim 1, and the claims dependent thereon, to delete the term "comprising" and substitute therefore the term "consisting essentially of," applicant has excluded from the claims material elements disclosed in *Bunick et al.*, specifically the cellulose, which affect the basic and novel characteristics of applicant's invention.

*Bunick et al.* also requires the use of 7 to 12% moisture. As set out above, applicant has amended independent claim 1 to recite "water in an amount up to about 5% by weight.

Furthermore, applicant uses only emulsifiers, not proteins as whipping agents as claimed in *Bunick et al.* *Bunick et al.* requires the use of whipping agents to prepare his frappe preparation with cellulose separately.

*Walter et al.* discloses chewy supplemental dietary fiber fortified taffy confections containing sugars, not sugar-free materials. Applicant's composition is a sugar-free soft chew tablet. The behavior of sugars, corn syrups, particularly fondant sugars is completely different from that of sugar-free materials such as polyols. Sugars are di- and polysaccharides. Polyols are polyhydric alcohols with C3-C6 hexa-alcohols. Polyols are not polysaccharides like sugar.

Applicant submits that *Bunick et al.* and *Walter et al.* are not properly combinable. There is no teaching or disclosure in *Bunick et al.* or *Walter et al.* to employ the emulsifier in the chewy supplemental dietary fiber fortified taffy sugar confection of *Walter et al.* in the sugarless chewable aerated confectionery frappe compositions of *Bunick et al.* Even if the references were properly combinable, the combination of *Bunick et al.* and *Walter et al.* would still not provide applicant's sugar-free soft chew tablet composition because *Bunick et al.* teaches the use of cellulose that reduce the inherent excessive cold flow and stickiness associated with hydrogenated starch hydrolysate confections and *Walter et al.* teaches the use of sugars not applicant's sugar-free materials such as polyols.

In order for a combination of references to render an invention obvious, it must be obvious that their teachings can be combined. *In re Avery* (CCPA 1975) 518 F2d 1228, 186 USPQ 161. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the

combination. *In re Geiger* (CAFC 1987) 815 F2d 686, 2PQ2d 1276; *In re Fine* (CAFC 1988) 5 PQ2d 1596. When the incentive to combine the teachings of the references is not immediately apparent, it is the duty of the examiner to explain why the combination of the teachings is proper. *Ex parte Skinner* (BPAI 1986) 2PQ2d 1788. The mere fact that references can be combined does not render the resultant combination obvious unless the prior art also suggest the desirability of the combination. *Berghauser v. Dann. Comr. Pats.* (DCDC 1979) 204 USPQ 393; *ACS Hospital Systems, Inc. v. Montefiore Hospital* (CAFC 1984) 732 F2d 1572, 221 USPQ 929. Same, where the references expressly teach away from what the PTO contends is obvious from the references. *In re Grasselli et al.* (CAFC 1983) 713 F2d 731, 218 USPQ 769. The references, viewed by themselves and not in retrospect, must suggest doing what applicant has done. *In re Shaffer* (CCPA 1956) 229 F2d 476, 108 USPQ 326, *In re Skoll* (CCPA 1975) 523 F2d 1392, 187 USPQ 481.

The mere fact it is possible for two isolated disclosures to be combined does not render the result of that combination obvious absent a logical reason of record, which justifies the combination. *In re Regel et al.* (CCPA 1975) 526 F2d 1399, 188 USPQ 136. To properly combine two references to reach a conclusion of obviousness, there must be some teaching, suggestion or inference in either or both of the references, or knowledge generally available to one of ordinary skill in the art, which would have led one to combine the relevant teachings of the two references. *Ashland oil Inc. v. Delta Resins and Refractories, Inc. et al.* (CAFC 1985) 776 F2d 281, 227 USPQ 657; 5 PQ2d 1532.

Accordingly, the Examiner's rejection of claims 1, 3-5 and 7-15 under 35 U.S.C. §103(a) as being unpatentable over *Bunick et al.* in view of *Walter et al.* should be withdrawn.

Obviousness of a composition or process must be predicated on something more than it would be obvious "to try" the particular component recited in the claims or the possibility it will be considered in the future, having been neglected in the past. *Ex parte Argabright et al.* (POBA 1967) 161 U.S.P.Q. 703. There is usually an element of "obvious to try" in any research endeavor, since such research is not undertaken with complete blindness but with some semblance of a chance of success. "Obvious to try" is not a valid test of patentability. *In re Mercier* (CCPA 1975) 515 F2d 1161, 185 U.S.P.Q. 774; *Hybritech Inc. v. Monoclonal Antibodies, Inc.* (CAFC 1986) 802 F2d 1367, 231 U.S.P.Q. 81; *Ex parte Old* (BPAI 1985)

229 U.S.P.Q. 196; *In re Geiger* (CAFC 1987) 815 F2d 686, 2 U.S.P.Q.2d 1276. *In re Dow Chemical Co.* (CAFC 1988) F2d, 5 U.S.P.Q.2d 1529. Patentability determinations based on that as a test are contrary to statute. *In re Antonie* (CCPA 1977) 559 F2d 618, 195 U.S.P.Q. 6; *In re Goodwin et al.* (CCPA 1978) 576 F2d 375, 198 U.S.P.Q. 1; *In re Tomlinson et al.* (CCPA 1966) 363 F2d 928, 150 U.S.P.Q. 623. A rejection based on the opinion of the Examiner that it would be "obvious to try the chemical used in the claimed process which imparted novelty to the process does not meet the requirement of the statute (35 U.S.C. 103) that the issue of obviousness be based on the subject matter as a whole. *In re Dien* (CCPA 1967) 371 F2d 886, 152 U.S.P.Q. 550; *In re Wiaains* (CCPA 1968) 397 F2d 356, 158 U.S.P.Q. 199; *In re Yates* (CCPA 1981) 663 F2d 1054, 211 U.S.P.Q. 1149. Arguing that mere routine experimentation was involved overlooks the second sentence of 35 USC 103. *In re Saether* (CCPA 1974) 492 F2d 849, 181 U.S.P.Q. 36. The issue is whether the experimentation is within the teachings of the prior art. *In re Waymouth et al.* (CCPA 1974) 499 F2d 1273, 182 U.S.P.Q. 290. The fact that the prior art does not lead one skilled in the art to expect the process used to produce the claimed product would fail does not establish obviousness. *In re Dow Chem. Co.* (CAFC 1988) 5 U.S.P.Q.2d 1529.


The provisions of Section 103 must be followed realistically to develop the factual background against which the Section 103 determination must be made. It is not proper within the framework of Section 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of other parts necessary for the full appreciation of what such reference fairly suggest to one of ordinary skill in the art. The references of record fail to teach or suggest applicant's invention as a whole.



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In view of the foregoing Amendment and Response, applicants request reconsideration pursuant to 37 C.F.R. §112 and allowance of the claims pending in this application. Applicant requests the Examiner to telephone the undersigned attorney should the Examiner have any questions or comments, which might be most expeditiously handled by a telephone conference. No fee is deemed necessary in connection with the filing of this Amendment and Response. If any fee is required, however, authorization is hereby given to charge the amount of such fee to Deposit Account No. 13-4822.

Respectfully submitted,  
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